



July 27, 2020

Medrad, Inc.  
Amra Racic  
Senior Regulatory Affairs Specialist  
9055 Evergreen Blvd Nw  
Minneapolis, Minnesota 55433-8003

Re: K130381

Trade/Device Name: Angiojet Ultra Power Pulse Kit  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEW

Dear Amra Racic:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 29, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, [Gregory.Oconnell@FDA.HHS.gov](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

Gregory W.  
O'Connell -S

Digitally signed by Gregory  
W. O'Connell -S  
Date: 2020.07.27 08:02:16  
-04'00'

Gregory O'Connell  
Assistant Director  
Plaque Modification Devices Team  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



July 29, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

MEDRAD, INC.  
c/o Amra Racic  
Senior Regulatory Affairs Specialist  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433

Re: K130381

Trade/Device Name: AngioJet® Ultra Power Pulse® Kit  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous Flush Catheter  
Regulatory Class: Class II  
Product Code: KRA  
Dated: May 30, 2013  
Received: May 31, 2013

Dear Ms. Racic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Bram D. Zuckerman -S**

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** \_\_\_\_\_ **K130381** \_\_\_\_\_

**Device Name:** AngioJet® Ultra Power Pulse® Kit

### Indications for Use:

The AngioJet® Ultra Power Pulse Kit is intended for use only with the AngioJet Ultra Thrombectomy Sets indicated for the control and selective infusion of physician-specified fluids, including thrombolytic agents, into the peripheral vascular system using the AngioJet Ultra System.

Prescription Use ☒ X \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S  
2013.07.29 18:16:15 -04'00'

## **Section 5 – 510(k) Summary**

**Submitter:** MEDRAD, INC.  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003 USA

**Contact Person:** Amra Racic  
Senior Regulatory Affairs Specialist  
Phone: (763) 450-8500  
Fax: (763) 780-2227  
Email: amra.racic@bayer.com

**Date Prepared:** February 13, 2013

**Trade Name:** AngioJet® Ultra Power Pulse® Kit

**Classification:** 870.1210

**Product Code:** KRA

**Predicate** The subject device is equivalent to the following device:  
**Device(s):** • K052256 AngioJet® Xpeedior® 120 Catheter

**Device** AngioJet Ultra Power Pulse Kit enables the AngioJet Ultra Thrombectomy  
**Description:** Set to deliver a pulsed infusion of physician-specified fluid to a local treatment area. The AngioJet Ultra Power Pulse Kit includes a Y-set with vented bag spikes that are bonded to tubing. Each upper arm of the Y-tubing contains a tubing clamp, one white and one red.

The vented bag-spikes are used to access the standard intravenous saline solution bag used with the AngioJet Ultra System and a second intravenous bag, containing physician-specified fluid. The tube clamps are used to control the flow of the two fluids.

The physician-specified fluid is delivered using the AngioJet Ultra System, which includes the AngioJet Ultra Console and Thrombectomy Set.

**Intended Use:** The AngioJet Ultra Power Pulse Kit is intended for use only with AngioJet Ultra Thrombectomy Sets indicated for the control and selective infusion of physician-specified fluids, including thrombolytic agents, into the peripheral vascular system using the AngioJet Ultra System.

**Comparison to predicate:** A comparison of the modified device and the currently marketed AngioJet Power Pulse Kit show the following similarities:

- Same intended use.
- Same operating principle.
- Same technological characteristics.
- Same performance claims.

**Performance Data:** This submission is a result of material modification to use DEHP free tubing. Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the

following testing:

- Biocompatibility
  - Cytotoxicity (ISO 10993-5)
  - Intracutaneous Reactivity (ISO 10993-10)
  - Sensitization (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - Physiochemical (ISO 10993-18)
  - Pyrogenicity (ISO 10993-11)
  - Hemolysis (ISO 10993-4)
- Mechanical integrity
  - Clamp open/close
  - Leak
  - Component separation

**Conclusion:** MEDRAD, Inc. considers the AngioJet Ultra Power Pulse Kit to be substantially equivalent to the predicate device listed above. This conclusion is based upon the device similarities in functional design, indications for use, and principles of operation. Mechanical and Biocompatibility Testing summarized in Tables 2 and 3, verified that the new device material is substantially equivalent to the predicate devices.